### UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

	)	Case No. 2:09-cv-12830-AJT-DAS
IN RE CARACO PHARMACEUTICAL	)	
LABORATORIES, LTD. SECURITIES	)	CLASS ACTION
LITIGATION	)	
	)	ORAL ARGUMENT REQUESTED

# DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Defendants Caraco Pharmaceutical Laboratories, Ltd., Daniel H. Movens, Dilip Shanghvi and Sun Pharmaceutical Industries Ltd., through their undersigned attorneys, hereby move, pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4, the Court for an Order dismissing, with prejudice, Plaintiffs' Consolidated Amended Complaint for Violations of the Federal Securities Laws ("Amended Complaint"), *see* Docket Entry No. 23. This Motion is based upon the following: the accompanying Memorandum of Law in Support of Defendants' Motion to Dismiss the Complaint ("Memorandum of Law"); the Exhibits attached to Defendants' Memorandum of Law; all papers and pleadings on file in this case; such matters and facts of which this Court may take judicial notice; and the arguments of counsel herein.

Pursuant to Local Rule 7.1(a), counsel for Defendants sought concurrence from counsel for Plaintiffs with respect to the relief sought in this Motion. Plaintiffs' counsel did not concur in the relief sought, thereby requiring this Motion.

The Defendants respectfully request oral argument.

<sup>&</sup>lt;sup>1</sup> The first pleading here was filed on July 17, 2009. On February 11, 2010, the Plaintiffs filed their Amended Complaint.

WHEREFORE, for the reasons stated herein and in Defendants' Memorandum of Law, Defendants respectfully request that the Court dismiss the Complaint in its entirety with prejudice.

Dated: April 12, 2010 BRIGGS AND MORGAN, P.A.

s/ Frank A. Taylor

Frank A. Taylor Margaret Adamczyk Goetze 2200 IDS Center 80 South Eighth Street Minneapolis, MN 55402 Telephone: (612) 977-8400 Facsimile: (612) 977-8650

ftaylor@briggs.com mgoetze@briggs.com

Attorneys for Defendants

### UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

	_ )	Case No. 2:09-cv-12830-AJT-DAS
IN RE CARACO PHARMACEUTICAL	)	
LABORATORIES, LTD. SECURITIES	)	CLASS ACTION
LITIGATION	)	
	)	ORAL ARGUMENT REOUESTED

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Frank A. Taylor Margaret Adamczyk Goetze Briggs and Morgan, P.A. 2200 IDS Center 80 South Eighth Street Minneapolis, MN 55402 Telephone: (612) 977-8400 Facsimile: (612) 977-8650 ftaylor@briggs.com mgoetze@briggs.com

Attorneys for Defendants

## TABLE OF CONTENTS

			Pa	age
INTRODUC	TION			1
STATEMEN	T OF IS	SSUES	PRESENTED	5
CONTROLL	ING O	R MOS	T APPROPRIATE AUTHORITY	6
ARGUMEN'	T			7
I.	PLEA	ADING	STANDARDS	7
II.			S HAVE FAILED TO STATE A CLAIM FOR SECURITIES AINST THE DEFENDANTS	8
	A.		tiffs have failed to plead that the Defendants made presentations or omissions of material fact	8
		1.	The alleged misrepresentations related to Caraco's compliance with cGMP are not material	8
		2.	None of the Defendants had a duty to predict what action the FDA would take in response to the FDA's inspectional observations and issuance of a warning letter	. 13
	B.		tiffs have failed to allege facts giving rise to a strong ence of fraudulent intent on the part of any of the Defendants	. 16
		1.	Plaintiffs fail to allege facts sufficient to satisfy the <i>Helwig</i> factors for any Defendant	. 17
		2.	Plaintiffs' assertion that management "must have known" about Caraco's non-compliance with cGMP does not support a strong inference of scienter	. 19
		3.	Allegations based on information from unnamed former employees of Caraco do not satisfy the scienter pleading requirements of the PSLRA	. 20
		4.	Plaintiffs also fail to allege facts sufficient to infer knowledge or recklessness with regard to statements regarding Caraco's commitment to remedying any cGMP violations	. 28
		5.	An individual's signature on an SEC Filing does not satisfy the element of scienter	. 30
		6.	The Amended Complaint fails to plead any motive for Defendants to commit the alleged fraud	. 30
	C.		Amended Complaint improperly group pleads its scienter ations	. 31
	D.		Amended Complaint fails to state a claim for securities fraud st Shanghvi	. 33

## TABLE OF CONTENTS

(continued)

Page

		1.	Plaintiffs cannot assert a fraud claim against Shanghvi based on his position with Caraco	33
		2.	Plaintiffs have failed to establish that Shanghvi's statements in a September 2008 news article were made with intent to deceive, manipulate, or defraud	33
	E.		mended Complaint fails to assert a claim for securities fraud t Sun Pharma	35
	F.	fail to	mended Complaint must also be dismissed because Plaintiffs specify each allegedly misleading statement and the reasons ach statement is misleading	36
		1.	Caraco's statement to investors that it changed leadership in the production area is true, as corroborated by a confidential witness	38
		2.	Caraco's general optimistic statements about its staff, training, quality assurance and quality control are not actionable as a matter of law	39
		3.	Caraco's forward-looking statements are entitled to protection under the PSLRA's "safe harbor" provision	40
III.			DED COMPLAINT FAILS TO STATE A CLAIM FOR ERSON LIABILITY	41
	A.	Plainti	ffs fails to allege an underlying securities violation	42
	В.	directo	ffs' summary conclusions that a corporate executive, or, and owner are control persons for purposes of Section are insufficient	42
	C.	Plainti	ffs have not satisfied the culpable participation test	43
CONCLUSIO	N	•••••		44

# TABLE OF AUTHORITIES

### **CASES**

Acito v. IMCERA Group, Inc., 47 F.3d 47 (2d Cir. 1995)20
Anderson v. Abbott Labs. 140 F. Supp. 2d 894 (N.D. Ill. 2001), aff'd, 269 F.3d 806 (7th Cir. 2001) 3, 6, 12-13
Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009)
Ballan v. Wilfred Am. Educ. Corp., 720 F. Supp. 241 (E.D.N.Y. 1989)20
Basic, Inc. v. Levinson, 485 U.S. 224 (1988)
Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007)
Bovee v. Coopers & Lybrand C.P.A., 272 F.3d 356 (6th Cir. 2001)19
Chill v. General Elec. Co., 101 F.3d 263 (2d Cir. 1996)36
City of Monroe Employees Ret. Sys. v. Bridgestone Corp., 399 F.3d 651 (6th Cir. 2005)6, 11, 35, 39
D.E. & J P'ship v. Conway, 284 F. Supp. 2d 719 (E.D. Mich. 2003)
Darby v. Century Bus. Servs., Inc., 96 F. App'x 277, 2004 WL 690056 (6th Cir. Mar. 30, 2004)35
Eisenberg v. Gagnon, 766 F.2d 770 (3rd Cir. 1985)20
EP Medsystems, Inc. v. EchoCath, Inc., 235 F.3d 865 (3d Cir. 2000)
Florida State Bd. of Admin. v. Green Tree Fin. Corp., 270 F.3d 645 (8th Cir. 2001)30
Frank v. Dana Corp., 649 F. Supp. 2d 729 (N.D. Ohio 2009)17, 43

547 F.3d 564 (6th Cir. 2008)	Passim
Harps v. TRW Auto. U.S., LLC, No. 09-3214, 2009 WL 3583605 (6th Cir. Nov. 3, 2009)	7
Havenick v. Network Express, Inc., 981 F. Supp. 480 (E.D. Mich. 1997)	37
Helwig v. Vencor, Inc., 251 F.3d 540 (6th Cir. 2001)	Passim
Higginbotham v. Baxter Int'l Inc., 495 F.3d 753 (7th Cir. 2007)	6, 22
In re Baesa Sec. Litig., 969 F. Supp. 238 (S.D.N.Y. 1997)	36
In re Capstead Mortg. Corp. Sec. Litig., 258 F. Supp. 2d 533 (N.D. Tex. 2003)	42
In re Citigroup, Inc. Sec. Litig., 330 F. Supp. 2d 367 (S.D.N.Y. 2004)	30
In re Comshare Inc. Sec. Litig., 183 F.3d 542	30, 36
In re Credit Acceptance Corp. Sec. Litig., 50 F. Supp. 2d 662 (E.D. Mich. 1999)	33
In re Dep't 56, Inc. Sec. Litig., No. 01-CV-401, 2002 WL 924247 (D. Minn. May 1, 2002)	15
In re Discovery Labs. Sec. Litig., No. 06-1820, 2006 WL 3227767 (E.D. Pa. Nov. 1, 2006)	9
In re Ferro Corp., No. 1:04CV1440, 2007 WL 1691358 (N.D. Ohio June 11, 2007)	24
In re Ford Motor Co. Sec. Litig., 184 F. Supp. 2d 626 (E.D. Mich 2001)	6, 14
<i>In re Ford Motor Co. Sec. Litig.</i> , 381 F.3d 563 (6th Cir. 2004)	6, 8, 14, 39
In re Goodyear Tire & Rubber Co. Sec. Litig. 436 F. Supp. 2d 873 (N.D. Ohio 2006)	6. 37

In re Guidant Corp. Sec. Litig., 536 F. Supp. 2d 913 (S.D. Ind. 2008)	15
In re Hardinge, Inc. Sec. Litig., No. 08-CV-6490, 2010 WL 447397 (W.D.N.Y. Feb. 2, 2010)	19
In re Hayes Lemmerz Int'l Inc. Equity Sec. Litig., 271 F. Supp. 2d 1007 (E.D. Mich. 2003)	-23, 42
<i>In re Huffy Corp. Sec. Litig.</i> , 577 F. Supp. 2d 968	, 32, 35
In re Huntington Bancshares Inc. Sec. Litig., No. 2:07-cv-1276, 2009 WL 4666455 (S.D. Ohio Dec. 4, 2009)	29, 31
In re Lernout & Hauspie Sec. Litig., 208 F. Supp. 2d 74 (D. Mass. 2002)	32
In re Livent Inc. Noteholders Sec. Litig., 151 F. Supp. 2d 371 (S.D.N.Y. 2001)	43
In re Loral Space & Commc'ns Ltd. Sec. Litig., NO. 01 Civ. 4388, 2004 WL 376442 (S.D.N.Y. Feb. 27, 2004)	22
In re Proquest Sec. Litig., 527 F. Supp. 2d 728 (E.D. Mich. 2007)	21
In re Sunbeam Sec. Litig., 89 F. Supp. 2d 1326 (S.D. Fla. 1999)	32
In re Syntex Corp. Sec. Litig., 95 F.3d 922	18, 29
Indiana State Dist. Council of Laborers & Hod Carriers Pension & Welfare Fund v.  Omnicare, Inc., 583 F.3d 935 (6th Cir. 2009)	, 15, 39
Jennings v. County of Washtenaw, 475 F. Supp. 2d 692 (E.D. Mich. 2007)	27
Jones v. City of Cincinnati, 521 F.3d 555 (6th Cir. 2008)	35
Kalnit v. Eichler, 85 F. Supp. 2d 232 (S.D.N.Y. 1999)	42
Konkol v. Diebold, Inc., 590 F.3d 390 (6th Cir. 2009)	. 18. 26

Ley v. Visteon Corp., 543 F.3d 801 (6th Cir. 2008)	Passim
Mansbach v. Prescott, Ball & Turben, 598 F.2d 1017 (6th Cir. 1979)	16
Miller v. Champion Enters. Inc., 346 F.3d 660 (6th Cir. 2003)	6, 16, 41
Mishkin v. Ageloff, No. 97 Civ. 2690, 1998 WL 651065 (S.D.N.Y Sept. 23, 1998)	44
Miss. Pub. Employees' Ret. Sys. v. Boston Scientific Corp., 523 F.3d 75 (1st Cir. 2008)	18
Murphy v. Sofamor Danek Group, Inc., 123 F.3d 394 (6th Cir. 1997)	Passim
Picard Chem. Inc. Profit Sharing Plan v. Perrigo Co., 940 F. Supp. 1101 (W.D. Mich. 1996)	Passim
Pilarczyk v. Morrison Knudsen Corp., 965 F. Supp. 311 (N.D.N.Y. 1997)	37
PR Diamonds, Inc. v. Chandler, 364 F.3d 671 (6th Cir. 2004)	Passim
Public Pension Fund Group v. KV Pharmaceutical Co., — F. Supp. 2d —, 2010 WL 681443 (E.D. Mo. Feb. 22, 2010)	3, 6, 9-10
Robbins v. Moore Med. Corp., 894 F. Supp. 661 (S.D.N.Y. 1995)	9
Ronconi v. Larkin, 253 F.3d 423 (9th Cir. 2001)	19
Southland Sec. Corp. v. INSpire Ins. Solutions, Inc., 365 F.3d 353 (5th Cir. 2004)	32
Starkman v. Marathon Oil, 772 F.2d 231 (6th Cir. 1985)	14
Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308 (2007)	6-7, 16, 21
United Am. Health Care Corp. Sec. Litig., No. 2:05-cy-72112, 2007 WL 313491 (F.D. Mich. Jan. 30, 2007)	6 14 30 32

# Case 2:09-cv-12830-AJT-DAS Document 28 Filed 04/12/10 Page 10 of 55

United States v. BioPort Corp., 270 F. Supp. 2d 968 (W.D. Mich. 2003)	10
Wyser-Pratte Mgmt. Co. v. Telxon Corp., 413 F.3d 553 (6th Cir. 2005)	10
Zaluski v. United Am. Healthcare Corp., 527 F.3d 564 (6th Cir. 2008)	15
STATUTES	
15 U.S.C. § 77k	6
15 U.S.C. § 77m	6
15 U.S.C. § 77z1(a)(2)(A)(iv)	6
15 U.S.C. § 78u-4(b)	31
15 U.S.C. § 78u-4(b)(1)	2, 5, 7, 36
15 U.S.C. § 78u-4(b)(2)	6-7
15 U.S.C. § 78u-5(i)(1)(A-C)	6, 40
15 U.S.C. § 78u-5(c)(1)	6, 40
Mich. Comp. Laws § 15.362	27
OTHER AUTHORITIES	
21 C.F.R. § 20.101(a)	13

#### INTRODUCTION

Defendants,<sup>2</sup> by and through their undersigned counsel, respectfully submit this Memorandum of Law in support of their Motion, brought pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Federal Rules of Civil Procedure 9(b) and 12(b)(6), for an order dismissing Plaintiffs' Consolidated Amended Complaint ("Amended Complaint") in its entirety, with prejudice.

Plaintiffs have sued Caraco for alleged violations of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10(b)-5 promulgated thereunder<sup>3</sup> on behalf of a putative class of individuals who, from May 29, 2008 through June 25, 2009, purchased Caraco securities.

#### Plaintiffs allege that:

- i. Caraco, a generic drug manufacturer and distributor regulated by the Food and Drug Administration ("FDA"), misled its shareholders when it stated in various form filings with the Securities and Exchange Commission ("SEC") and elsewhere that "we believe we are substantially cGMP<sup>4</sup> compliant" (Am. Compl. ¶¶ 2, 102 & 103);
- ii. Caraco omitted to state that the FDA could impose severe sanctions upon the company should the FDA determine that Caraco was not substantially cGMP compliant (Am. Compl. ¶ 165);
- iii. Caraco's alleged misstatements and omissions of these supposed material facts caused the market to overvalue Caraco's common stock and, when the truth became known, the price of the common stock dropped, causing the investors to suffer a loss (Am. Compl. ¶¶ 149-151);

1

<sup>&</sup>lt;sup>2</sup> The Defendants are Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), Daniel H. Movens ("Movens"), Dilip Shanghvi ("Shanghvi") and Sun Pharmaceutical Industries Ltd. ("Sun Pharma).

<sup>&</sup>lt;sup>3</sup> Plaintiffs have sued former Caraco CEO Daniel H. Movens ("Movens"), Caraco Chairman of the Board Dilip Shanghvi ("Shanghvi") and Sun Pharmaceutical Industries Ltd. ("Sun Pharma") as alleged "control persons" of Caraco under Section 20(a) of the Exchange Act. Am. Compl. ¶¶ 187-190. From time to time, Movens and Shanghvi will be called the "Individual Defendants" in this paper. Caraco, Movens, Shanghvi and Sun Pharma shall be called "Defendants."

<sup>&</sup>lt;sup>4</sup> The term cGMP means current Good Manufacturing Practices.

- iv. Caraco and the other Defendants acted with *scienter* because the Defendants either knew or were reckless in not knowing that Caraco was not cGMP compliant and that the FDA might obtain an order requiring forfeiture of drugs manufactured by Caraco (Am. Compl. ¶¶ 159-164); and
- v. Sun Pharma and the Individual Defendants are liable under Section 20(a) of the Exchange Act by virtue of their alleged positions as "control persons" of Caraco. Am. Compl. ¶¶ 187-190.

The Plaintiffs, however, do not satisfy the stringent pleading requirements of Fed. R. Civ. P 9(b) and the PSLRA, and the Complaint must be dismissed, with prejudice.

The PSLRA established stringent pleading requirements for securities fraud actions such as this matter and provides "procedural protections to discourage frivolous litigation." *Helwig v. Vencor, Inc.*, 251 F.3d 540, 547 (6th Cir. 2001). Under the PSLRA, these Plaintiffs must (i) specify each statement alleged to be misleading; (ii) explain why each such statement is misleading; and (iii) state with particularity facts giving rise to a strong inference that the defendant acted with *scienter*. 15 U.S.C. § 78u-4(b)(1). Plaintiffs' Amended Complaint must be dismissed because it fails to satisfy the PSLRA's stringent pleading requirements.

Plaintiffs have failed to allege that Defendants made any misstatements of material fact. Throughout the putative class period, Caraco disclosed to investors that it had received Form 483s (inspectional observations) from the FDA, as well as a warning letter. In its Form 10-Ks, filed with the SEC for fiscal years 2008 and 2009, Caraco clearly disclosed the sanction that could be imposed for non-compliance. For example, on June 10, 2008, Caraco provided the following warning to investors: "Noncompliance with applicable [FDA] requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecutions." Exhibit A (Form 10-K, filed on June 10, 2008, p. 8). Because these documents are publicly available, the marketplace had full knowledge of issues raised by the FDA and range of sanctions the FDA could impose against Caraco.

Caraco's opinion that it was substantially compliant with current Good Manufacturing Practices is simply immaterial as a matter of law, because such an opinion is not the type of information that a reasonable investor would find important to the "total mix of information available" to investors. *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988). Indeed, the Eastern District of Missouri in *Public Pension Fund Group v. KV Pharmaceutical Co.*, — F. Supp. 2d —, 2010 WL 681443 (E.D. Mo. Feb. 22, 2010) provides guidance and the United States Court of Appeals for the Seventh Circuit teaches in *Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894 (N.D. Ill. 2001), *aff'd*, 269 F.3d 806 (7th Cir. 2001) that such opinions are simply not actionable as they do not constitute misstatements of material fact.

Moreover, Caraco had no duty to disclose to investors the likelihood that the FDA would initiate a forfeiture action because a future event is not a fact. Such an action is speculative until it occurs – if at all. The government's seizure of Caraco's drug products on June 25, 2009 was an unwelcome surprise for the Company, as well as its investors. Caraco's lack of clairvoyance does not constitute securities fraud.

Plaintiffs have failed to plead facts giving rise to the "strong inference" required by the PSLRA that any Defendant acted with *scienter* because the Amended Complaint (i) relies solely on non-credible allegations from anonymous, former Caraco employees; (ii) pleads fraud by hindsight; and (iii) alleges no motive to explain why Defendants sought to deceive investors. There are simply no allegations in the Amended Complaint that any of these Defendants did not reasonably believe that Caraco was substantially compliant with cGMP.

The Amended Complaint additionally fails to state a claim against Movens, Caraco's former chief executive officer, and Shanghvi, chairman of Caraco's Board of Directors (collectively, the "Individual Defendants") because Plaintiffs assert that the Individual

Defendants are liable based solely on their positions with Caraco. Federal courts, however, routinely reject securities fraud claims against corporate officers and directors where, as here, the Amended Complaint does nothing more than proceed on the basis of (i) group pleading and (ii) the mere allegation that, because of an officer's or director's position, he or she had access to information regarding the falsity of the representations.

Finally, because the Plaintiffs cannot establish a primary violation under the Exchange Act, their claim for "control person" liability brought against Sun Pharma and the Individual Defendants under Section 20(a) of the Exchange Act must also be dismissed.

#### STATEMENT OF ISSUES PRESENTED

- I. Whether Count I of the Complaint should be dismissed for failure to state a claim where Plaintiffs fail to allege that the Defendants made any misrepresentations or omissions of material fact?
- II. Whether Count I of the Complaint should be dismissed for failure to meet the requirements of Federal Rule of Civil Procedure 9(b) and the PSLRA because Plaintiffs have not stated with particularity facts giving rise to a strong inference that the Defendants acted with *scienter*?
- III. Whether Count I of the Complaint should be dismissed for failure to plead a duty to disclose the alleged omissions?
- IV. Whether Claim I of the Complaint should be dismissed because it fails to identify false statements made by the Defendants and the reasons such statements were false with the particularity required by Section 78u-4(b)(1) of the PSLRA?
- V. Whether Claim II of the Complaint should be dismissed for failure to plead primary liability under Section 10(b) of the Exchange Act and for failure to adequately plead control?

#### CONTROLLING OR MOST APPROPRIATE AUTHORITY

Fed. R. Civ. P. 9(b) and 12(b)(6)

15 U.S.C. § 78u-4(b)(2); 15 U.S.C. § 77k; 15 U.S.C. § 77m; 15 U.S.C. § 77z1(a)(2)(A)(iv); 15 U.S.C. § 78u-5(c)(1); 15 U.S.C. § 78u-5(i)(1)(A-C)

Anderson v. Abbott Laboratories, 140 F. Supp. 2d 894 (N.D. Ill. 2001)

Basic, Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)

City of Monroe Employees Ret. Sys. v. Bridgestone Corp., 399 F.3d 651, 675 (6th Cir. 2005)

D.E. & J P'ship v. Conway, 284 F. Supp. 2d 719, 736 (E.D. Mich. 2003)

In re Ford Motor Co. Sec. Litig., 184 F. Supp. 2d 626, 633 (E.D. Mich 2001)

*In re Ford Motor Co. Sec. Litig.*, 381 F.3d 563, 570-71 (6th Cir. 2004)

Frank v. Dana Corp., 547 F.3d 564, 569-70 (6th Cir. 2008)

In re Goodyear Tire & Rubber Co. Sec. Litig. 436 F. Supp. 2d 873, 904 (N.D. Ohio 2006)

Helwig v. Vencor Inc., 251 F.3d 540 (6th Cir. 2001)

Higginbotham v. Baxter Int'l Inc., 495 F.3d 753, 756-57 (7th Cir. 2007)

Konkol v. Diebold, Inc., 590 F.3d 390, 403 (6th Cir. 2009)

Ley v. Visteon Corp., 543 F.3d 801, 811 (6th Cir. 2008)

Miller v. Champion Enterprises, Inc., 346 F.3d 660, 672 (6th Cir. 2003)

Murphy v. Sofamor Danek Group, Inc., 123 F.3d 394, 400 (6th Cir. 1997)

Picard Chem. Inc. Profit Sharing Plan v. Perrigo Co., 940 F. Supp. 1101 (W.D. Mich. 1996)

PR Diamonds, Inc. v. Chandler, 364 F.3d 671 (6th Cir. 2004)

Public Pension Fund Group v. KV Pharm. Co., 2010 WL 68144 (E.D. Mo. Feb. 22, 2010)

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 321-22 (2007)

*United American Health Care Corp. Sec. Litig.*, No. 2:05-cv-72112, 2007 WL 313491 (E.D. Mich. Jan. 30, 2007)

#### **ARGUMENT**

# I. PLEADING STANDARDS OF FED. R. CIV. P. 12(B)(6), FED. R. CIV. P. 9(B) AND THE PSLRA

To survive a Rule 12(b)(6) motion to dismiss, a complaint "must contain enough facts to establish a 'plausible,' as opposed to a merely 'possible,' entitlement to relief." *Harps v. TRW Automotive, U.S., LLC*, No. 09-3214, 2009 WL 3583605, at \*4 (6th Cir. Nov. 3, 2009). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quotation omitted). Although a court must accept all well-pleaded factual allegations in a complaint as true, when evaluating a motion to dismiss, the court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

A claim under Section 10(b) of the Exchange Act must also satisfy the mandate of Federal Rule of Civil Procedure 9(b) that fraud allegations be stated with particularity. *Frank v. Dana Corp.*, 547 F.3d 564, 569-70 (6th Cir. 2008). The Sixth Circuit instructs that a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Id.* at 570 (quotation omitted).

The PSLRA imposes two additional requirements. First, a complaint must "specify each statement alleged to have been misleading," along with "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). Second, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). A complaint's allegations of *scienter* "must be cogent and compelling, thus strong in light of other explanations." *Tellabs*, 551 U.S. at 324.

# II. PLAINTIFFS HAVE FAILED TO STATE A CLAIM FOR SECURITIES FRAUD AGAINST THE DEFENDANTS.

To state a viable claim for securities fraud under Section 10(b) and Rule 10b-5 of the Exchange Act, a plaintiff must allege the following elements: (1) a material misrepresentation or omission of fact that the defendant had a duty to close; (2) *scienter*; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation. *Indiana State Dist. Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935, 942 (6th Cir. 2009).

A. <u>Plaintiffs have failed to plead that the Defendants made misrepresentations or omissions of material fact.</u>

A misrepresentation or omission is material if there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by a reasonable investor as having significantly altered the total mix of information made available." *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988). Before a court can find a defendant liable for non-disclosure, the defendant must have violated an affirmative duty of disclosure. *Murphy v. Sofamor Danek Group, Inc.*, 123 F.3d 394, 400 (6th Cir. 1997).

1. The alleged misrepresentations related to Caraco's compliance with cGMP are not material.

Caraco's statements to the public that it had "substantially" complied with cGMP are immaterial as a matter of law because such statements are, by definition, opinions. Federal courts uniformly hold that statements which "clearly constitut[e] the opinions of the speaker" are not the types of information that "a reasonable investor could find important to the total mix of information available." *In re Ford Motor Co. Sec. Litig.*, 381 F.3d 563, 570-71 (6th Cir. 2004) (quotation omitted); *see also EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 873 (3d Cir.

2000) ("Material representations must be contrasted with statements of subjective analysis or extrapolations, such as opinions, motives and instructions, or general statements of optimism, which 'constitute no more than puffery and are understood by reasonable investors as such."").

A reasonable investor in a pharmaceutical company like Caraco knows that FDA admonitions are a fact of life. *See, e.g., Robbins v. Moore Med. Corp.*, 894 F. Supp. 661, 674 (S.D.N.Y. 1995) ("The mere fact of an FDA investigation is not material; such inspections represent a routine aspect of business."); *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2006 WL 3227767, at \*2, \*11 (E.D. Pa. Nov. 1, 2006) (recognizing that, "in a highly regulated industry," Form 483s and FDA warning letters "are a reality of doing business").

Recently, another district court rejected similar allegations of securities fraud with respect to a company's receipt of FDA Form 483s. In *Public Pension Fund Group v. KV Pharmaceutical Co.*, — F. Supp. 2d —, 2010 WL 681443, at \*10 (E.D. Mo. Feb. 22, 2010), the plaintiffs alleged that the defendants' statements that KV Pharmaceutical was in "material compliance with cGMP" were false and misleading because the company knew of, but failed to disclose, "violations" identified by the FDA in Form 483s.

In granting the defendants' motion to dismiss, the Eastern District of Missouri held that plaintiffs failed to plead with sufficient particularity that KV Pharmaceutical's compliance statements were misrepresentations because the first page of every Form FDA 483, including the ones at issue here,<sup>5</sup> states that the "document lists observations made by the FDA representative(s) during the inspection" but does "not represent a final determination regarding [a company's] compliance." *Id.* at \*10-\*11. The court further noted that the FDA added this language to the Form 483 in recognition of "misuse of and concerns with the [Form 483]" to

9

<sup>&</sup>lt;sup>5</sup> The FDA Form 483s (dated June 11, 2008, December 22, 2008 and May 12, 2009) are attached hereto as Exhibits B, C and D.

resolve any "perceived ambiguity [that might] result in inaccurate conclusions about the compliance of an inspected firm." *Id.* at \*10.

KV Pharmaceutical provides guidance that this Court should dismiss the Amended Complaint. Any investor who read Caraco's public filings realized that the Company was under the FDA's microscope. As a matter of law, "where information is contained in a document filed with the SEC, the market has knowledge of such matters." Picard Chemical Inc. Profit Sharing Plan v. Perrigo Co., 940 F. Supp. 1101, 1123 (W.D. Mich. 1996).

During the putative class period, Caraco advised shareholders that it had received notifications (Form 483s) from the FDA regarding the regulator's observations of Caraco's manufacturing processes. Am. Compl. ¶¶ 106, 112, 114, 122 & 131. In fact, just 13 days into the putative class period, Caraco received an FDA Form 483, which is publicly accessible on the FDA's website. Exhibit B. On November 3, 2008, Caraco advised investors that it had received a warning letter from the FDA.<sup>6</sup> Am. Compl. ¶ 114. The list of alleged violations are clearly stated in the warning letter. Exhibit E.

Any shareholder could have pulled the warning letter, or the other publicly-available documents, from the FDA's website.<sup>7</sup> The second sentence of the warning letter states that the inspection from May 1 to June 11, 2008 "revealed significant deviations from current Good

<sup>&</sup>lt;sup>6</sup> The warning letter that Caraco received from the FDA on October 31, 2008 is attached as Exhibit E.

It is entirely appropriate for these Defendants to rely on publicly-available documents and those instruments cited by Plaintiffs in their Amended Complaint. On a motion to dismiss, the court may consider the facts alleged in the complaint, any documents attached or incorporated in the complaint, "and public documents of which the Court can take judicial notice." *United States v. BioPort Corp.*, 270 F. Supp. 2d 968, 971 (W.D. Mich. 2003) (citing *Jackson v. City of Columbus*, 194 F.3d 737, 745 (6th Cir. 1999); *see also Wyser-Pratte Mgmt. Co. v. Telxon Corp.*, 413 F.3d 553, 560 (6th Cir. 2005) (on a motion to dismiss, "the court may also consider other materials that are integral to the complaint, are public records, or are otherwise appropriate for judicial notice").

Manufacturing Practice Regulations (CGMP) regulations . . ." Exhibit E. Even a quick glance at the warning letter would have alerted an investor to the fact that the FDA did not believe that Caraco was fully compliant with cGMP. The letter clearly warns the public that Caraco's failure to "promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction." Exhibit E. Clearly, even before the FDA's issuance of a warning letter to Caraco, the investing public knew that one potential repercussion of an FDA warning letter was that the government could seize certain of the drugs manufactured by that company.<sup>8</sup>

According to Plaintiffs, FDA warnings to Caraco prior to and during the putative class period "placed the Defendants on notice of the severe, pervasive cGMP violations and related problems that plagued Caraco's facilities." Am. Compl. ¶ 160 (emphasis added). Not only is this statement factually inaccurate, Plaintiffs' argument has no merit because documents in the public domain would have also placed Caraco's shareholders on notice of any alleged cGMP violations. The information which Plaintiffs allege Defendants were "on notice of" was also available to any Caraco investor. "A number of courts have indeed suggested that misrepresentations about a fact already known to the marketplace are not actionable." *City of Monroe Employees Retirement System v. Bridgestone Corp.*, 399 F.3d 651, 675 (6th Cir. 2005).

Moreover, Caraco was candid with investors about the risks involved in investing in a pharmaceutical company that is subject to FDA regulation. Plaintiffs' assertion—that Caraco "implied to the company's investors that the violations posed a minimal risk to the company"

<sup>&</sup>lt;sup>8</sup> See FDA, http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicy GuidanceManual/ucm074666.htm (last visited April 12, 2010).

<sup>&</sup>lt;sup>9</sup> The Form 483 does not contain a list of cGMP violations; the Form 483 only contains "observations" and does not present a final FDA determination regarding the company's compliance. *See*, *e.g.*, Exhibit B, p. 1.

(Am. Compl. ¶ 165)—is simply untrue. Caraco adequately warned investors about the repercussions of violating cGMP: "Noncompliance with applicable [FDA] requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecutions." Exhibit A (Form 10-K, filed on June 10, 2008, p. 8) (emphasis added) & Exhibit F (Form 10-K, filed on June 15, 2009, p. 7) (emphasis added).

In a similar case involving another company's belief in its "substantial compliance" with FDA regulations, the Seventh Circuit affirmed the Northern District of Illinois' dismissal of a shareholder complaint. *Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894 (N.D. Ill. 2001), *aff'd*, 269 F.3d 806 (7th Cir 2001). Abbott Laboratories ("Abbott") received a warning letter from the FDA on March 17, 1999, but did not publicly disclose its receipt of the warning letter for six months. *Abbott Labs.*, 140 F. Supp. 2d at 900.

In a press release on September 29, 1999, Abbott disclosed the FDA's allegations, as well as pending consent decree negotiations, but contested the charges and stated that Abbott "believes that it is in substantial compliance with these regulations." *Id.* at 900-01. A little more than one month after its disclosure—on November 2, 1999—Abbott entered into a consent decree with the FDA in which it agreed to pay a \$100 million civil fine and withdraw 125 products from the market. *Id.* at 901.

The *Anderson* plaintiffs alleged that Abbott "omitted facts about its ongoing problems with the FDA from its public filing and statements." *Id.* In dismissing the complaint, the Northern District of Illinois noted that, when Abbott finally disclosed its compliance issues, Abbott "discussed the warning letter, the ensuing re-inspection and the government's threatened sanctions. These were all true at the time." *Id.* at 906. Abbott was merely expressing "its opinion about its own compliance." *Id.* at 907. "Abbott's maintenance of its innocence is not

<u>fraud</u>." *Id*. at 906 (emphasis added). Because the "risks were abundantly apparent" from the press release itself, "investors can evaluate this sort of posturing for what it is worth." *Id*. at 907.

A reasonable investor must likewise weigh Caraco's opinion of its "substantial" compliance with facts in the public domain and make his or her own decision regarding the risks of investing with the Company. *Sofamor Danek*, 123 F.3d at 402 ("any analyst could easily obtain a copy of the [warning] letter and could make an independent judgment of its significance"); *Helwig*, 251 F.3d at 560 ("In *Sofamor Danek*, the information claimed as adverse to the company had already been disclosed and was publicly available to permit an independent assessment by investors and analysts."). Because the investing public had access to the FDA's assessment of Caraco's compliance with Good Manufacturing Practices (*see* 21 C.F.R. § 20.101(a)) and knew of the sanctions for non-compliance, Caraco's opinion as to its compliance with FDA regulations is not the sort of information that would form the basis for a reasonable investment decision.

2. None of the Defendants had a duty to predict what action the FDA would take in response to the FDA's inspectional observations and issuance of a warning letter.

Plaintiffs allege that the FDA seizure "was the sort of drastic action that Defendants had known was possible or even likely, given their serious and pervasive compliance and quality control problems that they had concealed from the market." Am. Compl. ¶ 157. According to Plaintiffs, the Defendants:

- "failed to disclose to investors the full extent to which Caraco was egregiously non-compliant with cGMP." Am. Compl. ¶ 119.
- failed "to disclose to investors the true risk that [the May 12, 2009 Form 483] posed to Caraco." Am. Compl. ¶ 161(d).

• "concealed from the market the very real risk that Caraco's deliberate and aggressive mandate to push production at the expense of drug quality and regulatory compliance – and the resulting failures to comply with cGMP – would lead to FDA sanctions against the Company." Am. Compl. ¶ 152.

Essentially, Plaintiffs assert that Caraco failed to predict that it was going to be shut down by the FDA. But, even if Caraco thought that it was going to be the target of an FDA seizure action (which it did not believe to be the case), Caraco had no duty to report such a belief to investors because there was no <u>fact</u> to disclose.

The Sixth Circuit teaches that there is no duty to report "soft" information—i.e., "information that is uncertain," including predictions and matters of opinion. *Sofamor Danek*, 123 F.3d at 401-02; *In re Ford Motor Co. Sec. Litig.*, 381 F.3d at 569. "Soft" information must be disclosed only if it is "virtually as certain as hard facts." *Starkman v. Marathon Oil*, 772 F.2d 231, 241 (6th Cir. 1985). Commenting on the Sixth Circuit's decision in *Sofamor Danek*, this Court noted that because the public was aware of the FDA warning, "there was no further duty to disclose soft information such as predictions regarding future regulatory action or losses the company may suffer as a result." *In re United Am. Health Care Corp. Sec. Litig.*, No. 2:05-cv-72112, 2007 WL 313491, at \*8 (E.D. Mich. Jan. 30, 2007).

Caraco had no duty to offer investors a prediction as to what sanctions, if any, might flow from the warning letter. *In re Ford Motor Co. Sec. Litig.*, 184 F. Supp. 2d 626, 633 (E.D. Mich. 2001) ("Companies are under no duty to disclose predictions that are not substantially certain to hold."), *aff'd, In re Ford Motor Co. Sec. Litig.*, 381 F.3d 563 (6th Cir. 2004). It makes sense that Caraco had no duty, under the securities laws, to warn investors about an event that was not certain. If Caraco had made a prediction that the FDA was likely to initiate an enforcement

action, and the FDA never made such a move, the stock price would have likely dropped upon such news. In such event, the shareholders would have sued, claiming that Caraco acted recklessly. "This illustrates, we think, why predictions not 'substantially certain to hold,' like most matters of opinion, simply do not come within the duty of disclosure." *Sofamor Danek*, 123 F.3d at 402.

Caraco could not predict the future. It simply could not have known in advance that the FDA was going to initiate a seizure action. Obviously, such action is outside Caraco's control. See Zaluski v. United Am. Healthcare Corp., 527 F.3d 564, 576 (6th Cir. 2008) (concluding that "Defendants' failure to disclose the potential consequences of the payments to Ford, consequences which turn on decisions made by actors outside of Defendants' control, did not constitute the type of hard information that this Court considers to be actionable"); Indiana State District Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc., 583 F.3d 935, 947 (6th Cir. 2009) (no disclosure of soft information is required, "despite the generalized claim of 'legal compliance,'" where "the materiality of the alleged omission derives solely from predictions regarding the actions of third parties, particularly whether fines or other sanctions would be brought based on findings of regulatory violations") (emphasis added).

Caraco advised investors when it received the Form 483s and the warning letter from the FDA. Caraco acknowledged that it had some compliance "challenges" (Am. Compl. ¶ 131), and it warned investors about the risks to the Company if it failed to comply with cGMP. Caraco was required to do no more. <sup>10</sup> *In re Dep't 56, Inc. Sec. Litig.*, No. 01-CV-401, 2002 WL 924247,

<sup>&</sup>lt;sup>10</sup> See In re Guidant Corp. Sec. Litig., 536 F. Supp. 2d 913, 927, 929 (S.D. Ind. 2008) (holding that plaintiffs failed to plead with requisite particularity that medical device company's omission of product defect information rendered affirmative statements false or misleading and noted that Rule 10b-5 does not require companies to "ring an alarm bell" (*i.e.*, "a blatant declaration that the defects were serious and likely to jeopardize stock prices").

\*4 (D. Minn. May 1, 2002) ("As the company's problems developed, so did its disclosures. Neither the PSLRA, nor law, nor logic requires that a company perceive and advise the public of all of the effects of a problem as it develops; it is impossible to do so.").

B. Plaintiffs have failed to allege facts giving rise to a strong inference of fraudulent intent on the part of any of the Defendants.

These Plaintiffs must allege sufficient facts that conclusively establish the Defendants acted with *scienter*, "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193-94 (1976)). The Sixth Circuit has held that actual knowledge of the falsity of affirmative misrepresentations will satisfy the *scienter* requirement. *Miller v. Champion Enters., Inc.*, 346 F.3d 660, 672 (6th Cir. 2003). Furthermore, a high degree of recklessness may also satisfy the *scienter* requirement. *D.E. & J P'ship v. Conaway*, 284 F. Supp. 2d 719, 745 (E.D. Mich. 2003) *aff'd*, 133 Fed. Appx. 994 (6th Cir. 2005). Recklessness is "highly unreasonable conduct which is an extreme departure from the standards of ordinary care. While the danger need not be known, it must at least be so obvious that any reasonable man would have known of it." *Mansbach v. Prescott, Ball & Turben*, 598 F.2d 1017, 1025 (6th Cir. 1979).

In *Tellabs*, the United States Supreme Court prescribed a specific three-step analysis that district courts are to follow when considering a motion to dismiss private securities claims arising under Section 10(b). *Frank v. Dana Corp.*, 547 F.3d 564, 570 (6th Cir. 2008). First, the court must accept all factual allegations in the complaint as true. *Tellabs*, 551 U.S. at 322. Second, "courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial

notice." *Id.* (citation omitted). Third, "the district court must conduct a 'comparative inquiry' and assess the possible competing inferences that could be drawn from the allegations, including 'plausible nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Frank*, 547 F.3d at 571 (quoting *Tellabs*, 551 U.S. at 323-24).

1. Plaintiffs fail to allege facts sufficient to satisfy the Helwig factors for any Defendant.

Conspicuously absent from the Amended Complaint is any reference to the factors supporting an inference of *scienter* identified by the Sixth Circuit in *Helwig v. Vencor*, 251 F.3d 540 (6th Cir. 2001).<sup>11</sup> Plaintiffs make no allegations concerning: (1) insider trading at a suspicious time or in an unusual amount; (2) divergence between internal reports and external statements on the same subject; (3) evidence of bribery by a top company official; (4) existence of an ancillary lawsuit charging fraud by a company and the company's quick settlement of that suit; (5) disregard of the most current factual information before making statements; (6) disclosure of accounting information in such a way that its negative implications could only be understood by someone with a high degree of sophistication; (7) the personal interest of certain directors in not informing disinterested directors of an impending sale of stock; and (8) the self-interested motivation of defendants in the form of saving their salaries or jobs. *Helwig*, 251 F.3d at 552. Indeed, the fact that Plaintiffs make <u>no</u> allegations concerning eight of the nine *Helwig* factors weighs strongly against an inference of *scienter*.

Plaintiffs' *scienter* allegations relate, if at all, to only one *Helwig* factor: "closeness in time of an allegedly fraudulent statement or omission and the later disclosure of inconsistent information." *Helwig*, 251 F.3d at 552. Plaintiffs assert that "Caraco's reassurance to its

<sup>&</sup>lt;sup>11</sup> The factors outlined by the Sixth Circuit in *Helwig* "remain viable" after the United States Supreme Court's decision in *Tellabs. Frank v. Dana Corp.*, 649 F. Supp. 2d 729, 737 (N.D. Ohio 2009).

investors in the June 15, 2009 Form 10-K that it believed it was 'substantially cGMP compliant' was revealed to be untrue when, just days later on June 24, 2009, the United States Attorney for the Eastern District of Michigan filed the Forfeiture Complaint." Am. Compl. ¶ 161(e). The fact that the government filed a forfeiture action on June 24, 2009, however, is irrelevant to the *scienter* analysis.

Plaintiffs' attempt to allege fraud based on an unfortunate outcome is "the classic fraud by hindsight case where a plaintiff alleges that the fact that something turned out badly must mean defendant knew earlier that it would turn out badly." *Konkol v. Diebold, Inc.*, 590 F.3d 390, 403 (6th Cir. 2009) (quoting *Miss. Pub. Employees' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 91 (1st Cir. 2008)). The fact that a defendant's belief or opinion later "proves to be wrong in hindsight does not render the statement untrue when made." *In re Syntex Corp. Sec. Litig.*, 95 F.3d at 934 (citation omitted). There is no liability where "a plaintiff's claim rests on the assumption that the defendants 'must have known of the severity of their problems earlier because conditions became so bad later on." *Miss. Pub. Employees' Ret. Sys.*, 523 F.3d at 84 (quoting *In re Boston Tech., Inc. Sec. Litig.*, 8 F. Supp. 2d 43, 53 (D. Mass. 1998)). Simply because the government initiated a seizure action does not mean that Defendants did not believe that Caraco was in substantial compliance with cGMP at the time that the Company issued the challenged statements to the investing public.

2. Plaintiffs' assertion that management "must have known" about Caraco's non-compliance with cGMP does not support a strong inference of scienter.

Plaintiffs assert that information provided by so-called Confidential Witnesses<sup>12</sup> confirms that Caraco's problems "were so pervasive and so closely related with the company's primary

18

<sup>&</sup>lt;sup>12</sup> In the Amended Complaint, these people are given the labels "CW." Defendants will also use the acronym CW followed by the number given by the Plaintiffs to each witness.

operations that management could not have been unaware of the problems." Am. Compl. ¶ 163 & ¶ 164(d). According to Plaintiffs, the "violations were of such a simple, basic, pervasive and serious nature . . . that it creates strong and direct evidence of *scienter*." Comp. ¶ 160.

Specifically, CW8 claims that Caraco's problem of producing tablets that were too thick or too thin "was so rampant that it was common knowledge within the Company" and, therefore, "Movens must have known about the tablet compression problem." Am. Compl. ¶ 96(a). But these allegations do not substantiate Plaintiffs' claim that the Defendants acted with *scienter* because "Plaintiffs may not simply rely on the proposition that Defendants must have known or should have known of, and participated in, the fraud." *Bovee v. Coopers & Lybrand C.P.A.*, 272 F.3d 356, 361 (6th Cir. 2001); *In re Hardinge, Inc. Sec. Litig.*, No. 08-CV-6490, 2010 WL 447397, at \*15 (W.D.N.Y. Feb. 2, 2010) ("[A]n allegation that a defendant merely 'ought to have known' is not sufficient to allege recklessness.") (citation and quotation omitted).

Furthermore, even if Movens knew, his knowledge of the Company's compliance problems does not equate to fraud. Business problems alone are not sufficient to establish *scienter. See Ronconi v. Larkin*, 253 F.3d 423, 434 (9th Cir. 2001) ("Problems and difficulties are the daily work of business people. That they exist does not make a lie out of any of the alleged false statements.").

None of the Defendants thought that a seizure action was where the FDA was headed and, therefore, Defendants cannot be liable for failing to forecast this event. Even when there is pending investigation, it cannot be said that the government's action will be predictable. *See Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 52-53 (2d Cir. 1995) (two prior FDA inspections did not mandate that defendants predict that a third inspection would result in suspension of production of animal drug manufacturing—"defendants' lack of clairvoyance simply does not

constitute securities fraud"). The securities laws do not expect companies to be prescient. Ballan v. Wilfred Am. Educ. Corp., 720 F. Supp. 241, 248 (E.D.N.Y. 1989) (anti-fraud provisions in the securities laws do not require the prediction of the outcome of governmental investigations). Caraco's failure to anticipate a future event simply does not constitute securities fraud.

3. Allegations based on information from unnamed former employees of Caraco do not satisfy the scienter pleading requirements of the PSLRA.

The essence of Plaintiffs' Exchange Act claim is that statements in Caraco's press releases and filings with the SEC ("SEC Filings") were false and misleading because "the Defendants knew or were deliberately reckless in not knowing that Caraco was not substantially compliant." Am. Compl. ¶113. Unfortunately, for these Plaintiffs, "[i]t is well-settled that opinions such as these provide a basis for liability only under very limited circumstances." *D.E. & J P'ship*, 284 F. Supp. at 736. Such opinions are actionable under Section 10(b) "only if the speaker does not believe the opinion and the opinion is not factually well-grounded." *Id.* (emphasis added) (citing *Mayer v. Mylod*, 988 F.2d 635, 639 (6th Cir. 1993)); *see also Eisenberg v. Gagnon*, 766 F.2d 770, 776 (3rd Cir. 1985) (holding that statements of opinion only constitute actionable "false or misleading" statements under the securities laws if plaintiffs can plead and prove that they were made "without a genuine belief or reasonable basis"). In other words, these Plaintiffs must allege that Caraco did not genuinely believe that its statements were true.

Here, Plaintiffs have failed to allege that any of the Defendants made the statements without a genuine belief that Caraco was substantially compliant at the time those statements were made. Instead, Plaintiffs assert that "Defendants lacked any reasonable basis to state a belief that Caraco was 'substantially compliant." Am. Compl. ¶ 103(b) & ¶ 121(a).

In their attempt to meet the rigorous pleadings standards of the PSLRA, Plaintiffs rely *solely* on the allegations of Confidential Witnesses who are anonymous, former Caraco employees. Am. Compl. ¶ 164 ("Confidential witness statements demonstrate that the Defendants either knew about Caraco's manufacturing problems and egregious noncompliance with cGMP, or had direct access to information that would indicate as much."). This pleading strategy dooms Plaintiffs' Complaint because allegations from a confidential source "cannot be the *sole* basis for establishing *scienter* because, 'anonymity conceals information that its essential to the . . . comparative evaluation required by *Tellabs*." *In re Proquest Sec. Litig.*, 527 F. Supp. 2d 728, 739-40 (E.D. Mich. 2007) (quoting *Higginbotham v. Baxter Int'l Inc.*, 495 F.3d 753, 756-57 (7th Cir. 2007)).

Allegations based on anonymous sources must satisfy a strict legal standard. A complaint must identify sources with "sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *In re Hayes Lemmerz Int'l Inc. Equity Sec. Litig.*, 271 F. Supp. 2d 1007, 1016 n.8 (E.D. Mich. 2003) (citing *Novak v. Kosaks*, 216 F.3d 300, 313-14 (2d Cir. 2000)); *see also D.E. & J Ltd. P'ship*, 284 F. Supp. 2d at 739. Plaintiffs must identify the confidential witnesses with sufficient particularity and articulate "what, when, where, and how they knew" the alleged facts. *Ley v. Visteon Corp.*, 543 F.3d 801, 811 (6th Cir. 2008). Furthermore, even if a confidential source might presumably possess the information alleged, the source's allegation must still be compelling and sufficiently specific to raise a strong inference of *scienter. See In re Loral Space & Commc'ns Ltd. Sec. Litig.*, No. 01 Civ. 4388, 2004 WL 376442, at \*11 (S.D.N.Y. Feb. 27, 2004).

To determine whether a strong inference of *scienter* has been established, the Court "must evaluate what the complaint reveals and disregard what it conceals." *Higginbotham v. Baxter Int'l Inc.*, 495 F.3d 753, 757 (7th Cir. 2007). Allegations from confidential witnesses "must be discounted." *Ley*, 543 F.3d at 811 (quoting *Higginbotham*, 495 F.3d at 757). "Usually that discount will be steep." *Higginbotham*, 495 F.3d at 757. The allegations from the ten Confidential Witnesses identified in the Amended Complaint are unreliable and must be discounted for the following reasons.

First, all of the Confidential Witnesses are former Caraco employees. They were part of a large group of employees who were laid off as a result of the FDA's seizure action, and they may be resentful about being unemployed in the current economic environment. Am. Compl. ¶89 & ¶138. In light of the circumstances, the Confidential Witnesses' allegations are not compelling. *Higginbotham*, 495 F.3d at 757 ("It is hard to see how information from anonymous sources could be deemed 'compelling' . . . Perhaps these confidential sources have axes to grind.").

Second, Plaintiffs failed to plead "sufficient detail to put the Defendants on notice regarding the source of the information." *In re Hayes Lemmerz Int'l Inc. Equity Sec. Litig.*, 271 F. Supp. 2d at 1016 n.8. Although Plaintiffs provide vague job titles for the Confidential Witnesses, the Amended Complaint fails to provide all of the Confidential Witnesses' employment tasks and the location of their work. *See id.* (finding that plaintiffs' complaint included sufficient particularity to support the probability that employees in their positions would possess the information alleged where plaintiffs' allegations included the confidential sources' positions, employment tasks and location of their work).

Third, half of the Confidential Witnesses were not employed during the entire putative class period. Am. Compl. ¶¶ 92, 93, 97 & 98. Two were employed by Caraco for only one month out of the 13-month putative class period. Am. Compl. ¶ 93 & ¶ 97. Their absence during the putative class period undermines Plaintiffs' *scienter* allegations.

In fact, one of the Confidential Witnesses, who was not employed during the entire putative class period, provides information that is entirely consistent with Defendants' position. In its Form 10-Q, filed on July 25, 2008, Caraco stated: "Significant resources have also been spent to improve overall lab operations. Such expenditures demonstrate to the regulators, clients and shareholders that <u>upper management is continually committed to adding quality individuals to the work force.</u> . . ." Am. Compl. ¶ 106 (emphasis added). Plaintiffs assert that this statement was false and misleading. Am. Compl. ¶ 107.

CW1, however, actually corroborates Caraco's disclosures. CW1, who started working at Caraco less than two months after Caraco filed the July 25, 2008 Form 10-Q, stated that "Caraco's senior management hired him/her and others to address Caraco's history of problems." Am. Compl. ¶90. According to the Complaint, CW1 came to Caraco with over 25 years of experience working in the pharmaceutical industry. Am. Compl. ¶90. Thus, instead of supporting a strong inference of intent to commit fraud, CW1's statement evidences Caraco's public statement that "upper management is continually committed to adding quality individuals to the work force," the sincerity of Defendants' belief in Caraco's efforts to comply with cGMP, and Caraco's commitment to fix any perceived compliance deviations.

Fourth, the information provided by the Confidential Witnesses should not be "accorded much weight" because it is "vague and conclusory." *Ley*, 543 F.3d at 811. For example, the Confidential Witnesses claim that Caraco pressured its employees to produce more. *See*, *e.g.*,

Am. Comp. ¶ 103(c)(i) ("the Company was trying to make too many drugs at the same time") & Am. Compl. ¶ 103(c)(iv) ("the problem stemmed from the attitude of management to 'get the tablets out the door""). The fact that Caraco may have pushed its employees to increase production does not lead to an automatic finding of *scienter*. *See In re Ferro Corp.*, No. 1:04CV1440, 2007 WL 1691358, at \*13 (N.D. Ohio June 11, 2007) (recognizing that "while extreme pressure to make numbers may cause an employee . . . to commit fraud, the mere exertion of pressure by management is not fraud").

In addition, only one of Confidential Witnesses reported directly to Movens, and only two are able to provide facts regarding specific conversations that he/she had with Movens. Am. Compl. ¶ 98(b). CW5 states that when he/she "approached Movens because it was impossible to meet Mehta's [Director of Manufacturing] and Ajmera's [Vice President of Manufacturing] demands for continued production while developing new SOPs [standard operating procedures] every day, Movens replied that 'his hands were tied' because he reported to Sun Pharma." Am. Compl. ¶¶ 91(a), 93(h) & 93(i). CW5 also claims "he told Movens that the Company needed better compression machines in order to reduce tablet production problems." Am. Comp. ¶ 93(c). And CW4 asserts that he/she "told Movens that the 'Sejong' tablet press machines Caraco was using were not proper for producing a pharmaceutical grade product." Am. Compl. ¶ 93(c). Plaintiffs contend that CW4 and CW5 advised Movens to buy "Korsh" machines. 

Am. Compl. ¶ 93(c).

<sup>&</sup>lt;sup>13</sup> Plaintiffs' overarching critique is that Caraco claims it was substantially cGMP, even though the company knew that representation was inaccurate. Whether CW4 and CW5 advised Movens to replace the Sejong with a Korsch adds nothing to the *scienter* analysis as to this alleged misrepresentation. There is no cGMP regulation that dictates utilization of anything other than a Korsch tablet press machine constitutes a *per se* violation.

But, the Complaint fails to provide the dates on which CW4 and CW5 allegedly spoke to Movens regarding these issues. These conversations may very well have occurred outside the putative class period. *Ley*, 543 F.3d at 811 (dismissing securities fraud class action complaint because plaintiffs failed to allege the "who . . . what, when, where, and how" regarding the defendants' knowledge) (emphasis added).

One Confidential Witness incredulously claims that he told Kaushik Gandhi, Caraco's Vice President of Manufacturing, that "had the FDA come right then, they would have shut down the company." Am. Compl. ¶ 93 & ¶ 95(a). This comment does not give rise to a strong inference of intent to commit fraud because the Amended Complaint does not provide the date on which the employee allegedly made this statement to Mr. Gandhi. *See Ley*, 543 F.3d at 811 (finding allegations from anonymous sources to be too vague and conclusory where the plaintiffs failed to allege what, when, where, and how the defendants allegedly knew about the fraud) (emphasis added). The preceding sentence says that when CW7 "interviewed with the Company, he/she was 'amazed how things were running." Am. Compl. ¶ 95(a). If CW7 in fact made this statement to Mr. Gandhi at the time of his/her initial interview, then why did he/she accept the job?

CW7's statement is simply not believable. There is no reason why a person would decide to work for a pharmaceutical company if he/she truly thought that the FDA would close the company's operations. Consequently, CW7's allegation does not help Plaintiffs establish the requisite mental state because the former employee's undated statement is either too vague or wholly unreliable.

Fifth, the broad accusations from the anonymous sources fail to connect the Defendants to the alleged fraud. Instead, Plaintiffs rely on general statements from the Confidential

Witnesses, such as: Caraco had a "history of problems," the Company had "rampant manufacturing problems," and "the tablet compression problem . . . was so rampant that it was common knowledge within the Company." Am. Compl. ¶¶ 90, 93(a), 95(a) & 96(a).

The Sixth Circuit recently confronted similar pleading deficiencies in a securities class action complaint and held:

These generalized statements cannot substitute for *specific* facts through which a factfinder can strongly infer that the Defendants themselves knew of or recklessly disregarded the falsity of the earnings statements, especially because the majority of the Confidential Witnesses are not identified as having any contact or interaction with any of the Defendants.

*Konkol v. Diebold, Inc.*, 590 F.3d 390, 401 (6th Cir. 2009). This Court should likewise conclude that the vague claims provided by the former employees are insufficient to satisfy the PSLRA's stringent pleading requirements.

Finally, the Confidential Witnesses' statements should be disregarded in light of the fact that they failed to report their concerns directly to the FDA. According to "accounts from ten [c]onfidential [w]itnesses . . . appalling conditions existed in the company's Detroit facility, conditions which imperiled the lives of consumers of Caraco's products." Am. Compl. ¶7 (emphasis added). Curiously, however, none of the Confidential Witnesses notified the FDA of the allegedly dangerous conditions. This is particularly troubling in light of the fact that two of the former Caraco employees (CW1 and CW2) were actually involved with the FDA inspection. Am. Compl. ¶90(c) & ¶91(f).

Although CW1 and CW2 had an opportunity during the audits to alert FDA investigators in person of these alleged life-threatening conditions, they did not do so (nor do Plaintiffs claim that any of the Confidential Witnesses ever reported their concerns to the FDA). If any of the Confidential Witnesses had approached the FDA, they would have been shielded from

termination. The Michigan Whistleblowers' Protection Act ("WPA") protects employees from retaliation who know (or suspect) of a violation of state, local, or federal law, regulation or rule:

An employer shall not discharge, threaten, or otherwise discriminate against an employee regarding the employee's compensation, terms, conditions, location, or privileges of employment because the employee, or a person acting on behalf of the employee, reports or is about to report, verbally or in writing, a violation or suspected violation of a law or regulation or rule promulgated pursuant to law of this state, a political subdivision of this state, or the United States to a public body, unless the employee knows that the report is false, or because an employee is requested by a public body to participate in an investigation, hearing or inquiry held by that public body, or a court action.

Mich. Comp. Laws § 15.362.14

Despite these protections – and purportedly knowing that dangerous and life-threatening conditions existed at Caraco's facilities – none of the Confidential Witnesses reported any of the alleged wrongdoing to the FDA, raises serious concerns about the credibility of the Confidential Witnesses' accusations against the Defendants.

4. Plaintiffs also fail to allege facts sufficient to infer knowledge or recklessness with regard to statements regarding Caraco's commitment to remedying any cGMP violations.

Plaintiffs assert that Defendants' statements to the FDA "that Caraco would remedy its cGMP violations" are "untrue." Am. Compl. ¶ 165. To support this claim, Plaintiffs rely on the allegations of several Confidential Witnesses who assert that Movens "held and attended weekly, and eventually daily, meetings with Caraco employees to discuss quality issues." Am. Compl. ¶ 164(c). Once again, Plaintiffs have disproved their case, and established that Caraco was dedicated to remedying any cCMP violations.

<sup>&</sup>lt;sup>14</sup> The WPA's main purpose is to alleviate "the inability to combat corruption or criminally irresponsible behavior in the conduct of government or large businesses." *Jennings v. County of Washtenaw*, 475 F. Supp. 2d 692, 707 (E.D. Mich. 2007) (quoting *Dudewicz v. Norris-Schmid, Inc.*, 503 N.W.2d 645 (Mich. 1993)).

Caraco's commitment to cGMP is further validated by the fact that Caraco hired outside consultants to help it address any compliance deficiencies. *See* Am. Compl. ¶ 62 (in response to the June 11, 2008 Form FDA 483, Caraco advised the FDA that it would hire consultants to help correct the deficiencies); Am. Compl. ¶ 102 (in Fiscal Year 2008, Caraco hired outside companies "to audit both the laboratory and manufacturing areas of our Company in order to improve and or maintain our systems of operation"); Am. Compl. ¶ 112 (in Fiscal Year 2009, Caraco retained outside companies to audit both the laboratory and manufacturing areas of the Company) & Am. Compl. ¶ 131 (Caraco advised investors in its Annual Report, filed on June 15, 2009, that "Fiscal 2009 has seen several challenges in manufacturing and compliance ... we have third party consultants that are providing guidance on remediation for such improvements").

Caraco's use of outside consultants negates any inference that the Defendants acted with fraudulent intent.<sup>15</sup> In *In re Huffy Corp. Sec. Litig.*, shareholders challenged Huffy Corporation's claim that it had conducted extensive due diligence in connection with the acquisition of another company. 577 F. Supp. 2d 968, 975 (S.D. Ohio 2008). The *Huffy* court found that the plaintiffs did not allege a cogent inference of *scienter* noting:

Huffy retained two entities to assist in conducting due diligence. Considering that, in the mix of all information relevant to due diligence, this Court concludes that an inference that any one or more or all of those three Defendants acted knowingly is not as compelling as the competing inference that they may have been negligent.

*Id.* at 988-99.

<sup>&</sup>lt;sup>15</sup> See PR Diamonds, Inc. v. Chandler, 364 F.3d 671, 691 (6th Cir. 2004) (noting that "the fact that the Company hired a consultant to examine its accounting systems... counters an inference that the Individual Defendants were trying to keep the alleged accounting problems hidden from view").

In this case, the non-culpable explanation for Defendants' behavior is likewise more compelling than Plaintiffs' allegations of fraudulent intent. Once Caraco became aware of compliance issues, it implemented corrective actions. Caraco believed it was substantially compliant, even if the FDA ultimately concluded otherwise. Recently faced with a similar situation, United States District Court, Southern District of Ohio granted the defendants' motion to dismiss and concluded:

While ideally Huntington should have known better or should have known earlier, this information does not demonstrate that when the public statements were made, such statements were false. Huntington may have incorrectly believed it had adequate reserves, but the mere fact that those reserves eventually proved to be inadequate does not mean a false statement was made.

*In re Huntington Bancshares Inc. Sec. Litig.*, No. 2:07-cv-1276, 2009 WL 4666455, at \*12 (S.D. Ohio Dec. 4, 2009). This Court should similarly dismiss Count I of the Plaintiffs' Complaint.

5. An individual's signature on an SEC Filing does not satisfy the element of scienter.

Plaintiffs' final attempt to establish *scienter* also fails. Plaintiffs claim that Movens and Shanghvi are liable for securities fraud based on the fact that they signed Sarbanes-Oxley Certifications found in Caraco's Form 10-K. Am. Compl. ¶ 170.

Plaintiffs' allegations relating to Shanghvi's signatures on the 10-Ks are not probative of scienter because the allegations are verifiably false. Shanghvi did not sign Sarbanes-Oxley Certifications. *See* Exhibit A (Form 10-K, filed on June 10, 2008, Exs. 31.1, 31.2 & 32) & Exhibit F (Form 10-K, filed on June 15, 2009, Exs. 31.1, 31.2 & 32.1). While a court must generally accept as true all of a plaintiff's well-pleaded factual allegations, the court may

29

<sup>&</sup>lt;sup>16</sup> See In re Syntex Corp. Sec. Litig., 95 F.3d 922, 930 (9th Cir. 1996) (finding that the plaintiffs did not plead facts to show that defendants' statements regarding prediction of FDA approval for a certain drug were false when made because "the company could have known of problems in the testing procedures, planned to remedy those deficiencies, and still thought it would achieve FDA approval by the estimated date").

disregard allegations contradicted by facts established in other documents properly under the court's consideration. *See HMS Property Mgmt. Group, Inc. v. Miller*, 69 F.3d 537, 1995 WL 641308, at \*3 (6th Cir. 1995) ("a court may disregard allegations contradicted by facts established in exhibits attached to the pleading").

Regardless, a defendant's signature on a Form 10-K is not probative of *scienter* because that "certification is required of all corporate officers and directors and says nothing about the Defendants' intent in the present case." *In re United Am. Health Care Corp. Sec. Litig.*, No. 2:05-cv-72112, 2007 WL 313491, at \*17 (E.D. Mich. Jan. 30, 2007); *see also In re Citigroup*, *Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 380 (S.D.N.Y. 2004). Thus, as with Plaintiffs' other *scienter* allegations, this argument has no merit.

6. The Amended Complaint fails to plead any motive for Defendants to commit the alleged fraud.

Facts regarding a defendant's motive may be "relevant to pleading circumstances from which a strong inference of fraudulent *scienter* may be inferred." *In re Comshare Inc. Sec. Litig.*, 183 F.3d at 551 (quotation omitted). Where a complaint does not show motive, other allegations tending to show *scienter* must simply be stronger. *Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 660 (8th Cir. 2001).

Plaintiffs have not alleged any facts indicating that Defendants benefited from their alleged fraud. Nor is there any allegation of insider trading. In fact, Plaintiffs acknowledge that Sun Pharma increased its ownership of Caraco stock during the putative class period. Am. Compl. ¶ 46(g) & ¶ 46(h). Between March 31, 2008 and March 31, 2009, Sun Pharma's beneficial ownership of Caraco increased from 70% to 74%. *Id.* These facts undermine Plaintiffs' suggestion that Defendants engaged in securities fraud.

If Sun Pharma knew that Caraco was not compliant, it, as a rational investor, would have decreased—not increased—its ownership share, and, when the suppressed "truth" (according to the Plaintiffs) became known and the price dropped, Sun Pharma would have purchased Caraco securities. Indeed, "[a] number of courts have held that the absence of insider trading actually negates an inference of scienter." D.E. & J Ltd. Partnership, 284 F. Supp. 2d at 743 n.22 (citing In re SCB Computer Tech., Inc. Sec. Litig., 149 F. Supp. 2d 334, 349 (W.D. Tenn. 2001); In re Credit Acceptance Corp. Sec. Litig., 50 F. Supp. 2d 662, 677-78 (E.D. Mich. 1999); Bay v. Palmisano, 2002 WL 31415713, \*10 (E.D. La. Oct. 24, 2002)); see also PR Diamonds, Inc., 364 F.3d at 691 (noting that "the absence of inside sales dulls allegations of fraudulent motive"). Similarly, the acquisition of stock during the class period "works against" an inference of scienter. PR Diamonds, Inc., 364 F.3d at 691; In re Huntington Bancshares Inc. Sec. Litig., 2009 WL 4666455, at \*17. Considering all of Plaintiffs' scienter arguments are unavailing (see supra Section II.B and infra Sections II.C, II.D and II.E), the absence of any motive allegations exacerbates the flaws in Plaintiffs' Complaint and warrants dismissal of the Section 10(b) claims against all Defendants.

## C. The Amended Complaint improperly group pleads its *scienter* allegations.

Plaintiffs contend that the "Individual Defendants are liable for the false statements pleaded herein, as those statements were each 'group-published' information, the result of the collective actions of the Individual Defendants." Comp. ¶ 29. This approach fails to satisfy the PSLRA. "Compliance with Rule 9(b) should be reviewed as to each of the elements of the claim of fraud in a complaint and as to each of the named defendants because each defendant must be informed of the specific nature of his alleged participation in allegedly defrauding a plaintiff." *Picard Chem. Inc.*, 940 F. Supp. at 1114. The Plaintiffs fail to satisfy this requirement because they fail to attribute the alleged misstatements of omission to particular Defendants.

In addition, the PSLRA further requires plaintiffs to "state with particularity facts giving rise to a strong inference that *the defendant* acted with the required state of mind." 15 U.S.C. § 78u-4(b) (emphasis added). The Fifth Circuit Court of Appeals teaches that the phrase "the defendant" in the PSLRA "may only reasonably be understood to mean 'each defendant' in multiple defendant cases, as it is inconceivable that Congress intended liability of any defendants to depend on whether they were all sued in a single action or were each sued alone in several separate actions." *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 364-65 (5th Cir. 2004). Consequently, "the group pleading doctrine did not survive the passage of the PSLRA." *In re Huffy Corp. Sec. Litig.*, 577 F. Supp. 2d at 984 (citing *Southland Sec. Corp.*, 365 F.3d at 365). According to the Fifth Circuit,

The "group pleading" doctrine conflicts with the *scienter* requirement of the PSLRA because, even if a corporate officer's position supports a reasonable inference that he likely would be negligent in not being involved in the preparation of a document or aware of its contents, the PSLRA state of mind requirement is severe recklessness or actual knowledge.

Southland Sec. Corp., 365 F.3d at 365.

Finally, "even assuming *arguendo* that the group pleading (or group publication) doctrine survived the passage of the PSLRA, those courts that have continued to apply the group pleading doctrine have held that *scienter* must be pled separately as to *each* defendant." D.E. & J Ltd. Partnership, 284 F. Supp. 2d at 742; In re United Am. Healthcare Corp. Sec. Litig., 2007 WL 313491, at \*16.

<sup>&</sup>lt;sup>17</sup> E.g., In re Sunbeam Sec. Litig., 89 F. Supp. 2d 1326, 1341 (S.D. Fla. 1999) (group pleading does not apply to the PSLRA's scienter requirements); In re Lernout & Hauspie Sec. Litig., 208 F. Supp. 2d 74, 84 (D. Mass. 2002) ("This doctrine does not, however, obviate the requirement that a court evaluate separately the allegations concerning the scienter of each of the individual defendants.").

Plaintiffs admit that they are relying on group-pleading to assert their fraud claims against the Individual Defendants. Am. Compl. ¶ 29. By their own acknowledgement, therefore, Plaintiffs have failed to comply with the pleading requirements of Rule 9(b) and the PSLRA. Thus, Plaintiffs' claims for securities fraud against the Individual Defendants must be dismissed.

D. The Amended Complaint fails to state a claim for securities fraud against Shanghvi.

Plaintiffs assert additional *scienter* allegations as to Shanghvi based on his (i) position with Caraco; and (ii) comments to a journalist.

1. Plaintiffs cannot assert a fraud claim against Shanghvi based on his position with Caraco.

Plaintiffs attempt to hold Shanghvi liable based on the fact that he is chairman of Caraco's Board of Directors. Comp. ¶¶ 28, 29 & 47. Plaintiffs assert that Shanghvi is liable based on his position and access to material non-public information. Am. Compl. ¶ 29. This allegation simply fails to meet the PSLRA's requirements. *See PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 688 (6th Cir. 2004) ("Contrary to Plaintiffs' assertions, fraudulent intent cannot be inferred merely from the Individual Defendants' positions in the Company and alleged access to information."); *D.E. & J Ltd. Partnership*, 284 F. Supp. 2d at 743 ("Courts have routinely rejected the attempt to plead *scienter* based on allegations that because of the defendants' board membership and/or their executive managerial positions, they had access to information concerning the company's adverse financial outlook."); *In re Credit Acceptance Corp. Sec. Litig.*, 50 F. Supp. 2d at 676 (alleging defendants knew or should have known of the fraud because of their positions in a company does not raise a strong inference of *scienter*).

2. Plaintiffs have failed to establish that Shanghvi's statements in a September 2008 news article were made with intent to deceive, manipulate, or defraud.

Besides the bare-bones assertion of his position at Caraco, the only other reference to Shanghvi's state of mind appears on pages 76 through 78 of the Complaint. In a telephonic interview, Shanghvi spoke to a reporter from the *Business Standard*, an Indian publication, about Sun Pharma, an Indian company. Am. Compl. ¶ 108. Shanghvi stated: "We are consistently focused on quality and greater scrutiny will only strengthen our vigil." Am. Compl. ¶ 108.

Plaintiffs' fraud claim against Shanghvi fails because a strong inference of *scienter* cannot be inferred from an article in which Shanghvi is principally talking about Sun Pharma, not Caraco. Even Plaintiffs acknowledge that the title of the article is: "Sun Pharma expects 25% growth in US." Am. Compl. ¶ 108. The article is about Sun Pharma; Caraco is only mentioned because it is a subsidiary of Sun Pharma. Am. Compl. ¶ 108. Therefore, when Shanghvi refers to "we," it is unclear as to whether he is referring to Sun Pharma or Sun Pharma and Caraco or Sun Pharma, Caraco and Sun Pharma's other subsidiary or some other combination of these entities.

Moreover, Plaintiffs fail to provide any facts to support their notion that Shanghvi acted with *scienter*. Plaintiffs assert that Shanghvi's statement is false and misleading "for the reasons stated" in Paragraphs 101 and 103 of the Amended Complaint. Am. Compl. ¶ 109. The only specific allegation regarding Shanghvi in those Paragraphs comes from a Confidential Witness. Plaintiffs assert: "Sometimes, CW10 would speak directly with Defendant Shanghvi." Am. Compl. ¶ 103(c)(v). What exactly CW10 spoke to Shanghvi about, however, is a mystery. Plaintiffs provide absolutely no details regarding any conversations between CW10 and Shanghvi. This is not the makings of a fraud case.

The Amended Complaint's failure to tie Shanghvi's knowledge at the time of the quote in the *Business Standard* with statements that he made to CW10 is a fatal defect. In *D.E. & J Ltd. Partnership v. Conaway*, this Court held that the plaintiffs there failed to adequately allege that the defendants acted with the requisite *scienter* because the complaint did not allege that defendants were "aware of any fact, discussion, meeting or memorandum that would have put them on notice of any alleged fraud." 284 F. Supp. 2d 719, 744 (E.D. Mich. 2003). Plaintiffs' Amended Complaint likewise fails to allege facts that support a strong inference of *scienter* on the part of Shanghvi and, therefore, all claims against him must be dismissed.

# E. The Amended Complaint fails to assert a claim for securities fraud against Sun Pharma.

Nowhere in the 140-page Amended Complaint do Plaintiffs allege that Sun Pharma made any false or misleading statements during the putative class period. Nor do Plaintiffs allege that Sun Pharma had any role in preparing any of the public disclosures. *See City of Monroe Employees Retirement Sys. v. Bridgestone Corp.*, 399 F.3d 651, 690 (6th Cir. 2005) (dismissing securities fraud claim where plaintiffs failed to allege that the defendant "played any role in drafting, reviewing or approving" the company's annual reports). Plaintiffs' failure to identify any allegedly false or misleading statement made by Sun Pharma, or even Sun Pharma's role in the creation of the misleading statements, warrants dismissal of Count I as to Sun Pharma. *See Darby v. Century Bus. Servs., Inc.*, 96 Fed. Appx. 277, 282, 2004 WL 690056, at \*4 (6th Cir. Mar. 30, 2004) (noting that plaintiffs fail to meet the heightened pleading standard of the PSLRA where the "complaint does not list a single statement alleged to be misleading"). "Simply stated, one cannot make a statement with *scienter* or fraudulent intent, if he does not make a statement." *In re Huffy Corp. Sec. Litig.*, 577 F. Supp. 2d at 988-99.

Plaintiffs' Amended Complaint fails to allege that Sun Pharma made any misstatements or omissions of material fact. Instead, the Amended Complaint falls back on the improper group pleading technique making a general allegation that all of the Defendants participated in a scheme to defraud the putative class members. Am. Compl. ¶177. Plaintiffs' conclusory allegation is insufficient and this Court should not accept this (or any other) legal conclusion as true when considering Defendants' Motion to Dismiss. *Jones v. City of Cincinnati*, 521 F.3d 555, 559 (6th Cir. 2008) (acknowledging that courts "need not accept as true legal conclusions"). In addition, Plaintiffs' use of group pleading does not comply with the PSLRA or Rule 9(b). *See supra* Section II.C.

Finally, Plaintiffs do not satisfy their *scienter* pleading obligations merely by connecting Sun Pharma, a company headquartered in India, to Caraco, its United States subsidiary. Am. Compl. ¶ 53. Investors know that Sun Pharma is Caraco's majority shareholder. Am. Compl. ¶ 30. The relationship between the two companies, however, is insufficient to subject Sun Pharma to liability for fraudulent statements allegedly made by Caraco to Caraco investors. A subsidiary's fraud cannot be automatically imputed to its corporate parent. *In re Comshare Inc. Sec. Litig.*, 183 F.3d at 554 ("Indeed, this Court should not presume recklessness or intentional misconduct from a parent corporation's reliance on its subsidiary's internal controls."); *see also Chill v. General Elec. Co.*, 101 F.3d 263, 270-71 (2d Cir. 1996); *In re Baesa Sec. Litig.*, 969 F. Supp. 238, 242 (S.D.N.Y. 1997). Thus, Plaintiffs' Section 10(b) claim against Sun Pharma must be dismissed.

F. The Amended Complaint must also be dismissed because Plaintiffs fail to specify each allegedly misleading statement and the reasons why each statement is misleading.

Plaintiffs have failed to specifically identify all of the statements that they claim constitute misrepresentations. Under the PSLRA, Plaintiffs must "specify each statement alleged

to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). Plaintiffs' attempt to comply with this requirement ostensibly appears in Sections VIII and IX of the Complaint. Am. Compl. ¶¶ 99-132. The Amended Complaint lumps certain press releases and SEC Filings, which span more than a 12-month time period, into one unwieldy 44-page segment. Am. Compl. ¶¶ 99-71.

In a few places, Plaintiffs highlight certain language with the use of bold and italicized type. This pleading technique is inadequate. For example, Paragraph 100 of the Amended Complaint provides two pages' worth of quotes from a press release issued by Caraco on May 29, 2008. Am. Compl. ¶ 100. In the following paragraph, Plaintiffs allege that the "foregoing statement was materially false and/or misleading when made . . ." Am. Compl. ¶ 101 (emphasis added). They refer to the word "statement" in the singular. There is no way for the Defendants or this Court to know which particular statement from the lengthy preceding block quote is the one that the Plaintiffs claim was fraudulent.

Plaintiffs should have pled their fraud claim on a statement-by-statement basis. *In re Goodyear Tire & Rubber Co. Sec. Litig.*, 436 F. Supp. 2d 873, 904 (N.D. Ohio 2006). "It is Plaintiffs' burden to plead fraud on a statement-by-statement basis, and they may not evade that requirement by requiring the Court to try to match the allegedly fraudulent statements to the allegations of wrongdoing that are scattered throughout the seventy-plus page Amended Complaint." *Id.* 

Instead of identifying each allegedly fraudulent statement, Plaintiffs impermissibly direct the Court to numerous press releases and SEC Filings and summarily conclude that the statements are fraudulent. Quoting extensively from press releases and SEC Filings, however, does not satisfy the PSLRA. *Havenick v. Network Express, Inc.*, 981 F. Supp. 480, 526 (E.D.

Mich. 1997) (dismissing a securities fraud complaint with prejudice where the plaintiffs "have simply compiled a long list of block quotes, many of which contain statements that cannot seriously be regarded as false or misleading, and they line these statements up against a conclusory list of omissions and pronounce that fraud exists"); *Pilarczyk v. Morrison Knudsen Corp.*, 965 F. Supp. 311, 321 (N.D.N.Y. 1997) ("broad allegation of fraud as to extensively quoted press releases and reports failed to adequately identify how each statement was fraudulent or misleading") (citation omitted). Because of Plaintiffs' fundamental pleading error, the PSLRA dictates that the Court must dismiss the Amended Complaint.

The only discernable place in the entire 140-page Amended Complaint in which Plaintiffs appear to identify sentences from one of Caraco's SEC Filings appears towards the end of the Amended Complaint. Plaintiffs assert that the following statements from Caraco's February 3, 2009 Form 10-Q are false and/or misleading:

- "We have changed the leadership in our production area in order to better align this area with our corporate goals."
- "We are disciplined and have the aptitude to execute our plan."
- "Our current focus is on manufacturing and quality assurance."
- "We continue to focus on improving the amount of support in quality assurance, quality control and manufacturing areas in order to continually improve the performance of our quality system."

Am. Compl. ¶ 123. The statements identified in Paragraph 123, however, fail to support Plaintiffs' fraud claim because they are (i) true, (ii) immaterial as a matter of law and/or (iii) protected by the PSLRA's safe harbor provision.

1. Caraco's statement to investors that it changed leadership in the production area is true, as corroborated by a confidential witness.

Caraco advised investors in its Form 10-Q for the 2009 fiscal third quarter that the company "changed the leadership in our production area in order to better align this area with our corporate goals." Am. Compl. ¶ 122 & ¶ 123. Although Plaintiffs allege in one part of their Amended Complaint that this statement is false (Am. Compl. ¶ 123), allegations in an earlier section of the Amended Complaint confirm that this statement is accurate.

Caraco filed its Form 10-Q on February 2, 2009. Am. Compl. ¶ 122. Less than two months before the issuance of the Form 10-Q, Caraco changed its leadership in both manufacturing and quality control. Am. Compl. ¶ 122. According to CW5, Caraco replaced two senior managers in December 2008. Am. Compl. ¶ 93(h). Plaintiffs acknowledge that the Company hired a new Director of Manufacturing and a new Vice President of Manufacturing shortly before Caraco filed its Form 10-Q. Thus, Caraco's statement in the Form 10-Q is not false.

2. Caraco's general optimistic statements about its staff, training, quality assurance and quality control are not actionable as a matter of law.

The statements highlighted by Plaintiffs are not actionable because they amount to nothing more than corporate optimism. In the Sixth Circuit, "liability does not attach to mere corporate puffery or statements of corporate optimism." *Omnicare*, 583 F.3d at 943. Statements of self-praise and statements expressing confidence in the company's future are immaterial puffery. *City of Monroe*, 399 F.3d at 671. Courts have consistently found immaterial "a certain kind of rosy affirmation commonly heard from corporate managers and numbingly familiar to the marketplace-loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important." *In re Ford Motor Co. Sec. Litig.*, 381 F.3d at 570-71 (quotation omitted).

Caraco's statements regarding its plans and goals are clearly vague and optimistic predictions that are immaterial as a matter of law. *Omnicare*, 583 F.3d at 944 (finding complaint failed to allege a material misstatement or omission where the corporate comment was "so banal and ubiquitous that it cannot engender reliance by reasonable investors"). Thus, even if the statements selected by Plaintiffs are false<sup>18</sup> (they are not), the statements are nevertheless immaterial because they are too insufficiently specific for a reasonable investor to find them important to the total mix of information available.

3. Caraco's forward-looking statements are entitled to protection under the PSLRA's "safe harbor" provision.

The PSLRA has created a "safe harbor" provision for forward-looking statements where those statements are "accompanied by meaningful cautionary statements." 15 U.S.C. § 78u-5(c)(1). Forward-looking statements apply to projections regarding revenue, income, earnings, statements about managements' plans or objectives, and statements involving future economical performance. 15 U.S.C. § 78u-5(i)(1)(A-C). "The safe harbor was designed to encourage company disclosure of future plans and objectives by removing the threat of liability." *Helwig*, 251 F.3d at 559 (citation omitted).

Caraco's disclosures during the putative class period regarding the Company's plans and goals fall within the protection of the safe harbor because they are clearly forward looking. Caraco's SEC Filings advised investors that words such as "believes," "plans," "expects," and other similar expressions are intended to identify forward-looking statements. Exhibit A (Form 10-K, filed on June 10, 2008, p. 1); Exhibit G (Form 10-Q, filed on July 25, 2008, p. 30); Exhibit H (Form 10-Q, filed on October 24, 2008, p. 34); Exhibit I (Form 10-Q, filed on February 3,

<sup>&</sup>lt;sup>18</sup> When evaluating whether a statement is material in the context of a Rule 10b-5 claim, it is irrelevant whether that statement is false or incomplete "if the misrepresented fact is otherwise insignificant." *Basic v. Levinson*, 485 U.S. 224, 238 (1988).

2009, p. 34); Exhibit F (Form 10-K, filed on June 15, 2009, p. 1). Caraco disclosed that the reports contain forward-looking statements that "are not guarantees of future performance and are subject to risks and uncertainties that cannot be predicted or quantified." *Id*.

Caraco's statements about future plans, expectations and goals were accompanied by cautionary language. For example, Caraco told investors that two of its "plans" for Fiscal 2009 and 2010 were "continue to focus and improve on FDA compliance" and "increase cGMP training to accommodate growing staff and compliance." Exhibit G (Form 10-Q, filed on July 25, 2008, p. 29); Exhibit H (Form 10-Q, filed on October 24, 2008, p. 33); Exhibit I (Form 10-Q, filed on February 3, 2009, p. 33). At same time, however, Caraco warned investors that one risk or uncertainty of investing with Caraco was the "lack of success in attaining full compliance with regard to regulatory and cGMP compliance." Exhibit G (Form 10-Q, filed on July 25, 2008, p. 29); Exhibit H (Form 10-Q, filed on October 24, 2008, p. 30); Exhibit I (Form 10-Q, filed on February 3, 2009, p. 34).

Because Caraco's cautionary language relates directly to the allegedly fraudulent statements, the statements are protected under the PSLRA's safe harbor provision and the Defendants' state of mind is irrelevant. *See Miller v. Champion Enterprises, Inc.*, 346 F.3d 660, 672 (6th Cir. 2003) (acknowledging that "if the statement qualifies as 'forward-looking' and is accompanied by sufficient cautionary language, a defendant's statement is protected regardless of the actual state of mind"). Thus, any statements regarding Caraco's goals, predictions and plans cannot form the basis for a securities fraud claim.

# III. THE AMENDED COMPLAINT FAILS TO STATE A CLAIM FOR CONTROL PERSON LIABILITY.

Plaintiffs contend that Sun Pharma (Caraco's majority shareholder), Movens (Caraco's CEO), and Shanghvi (Chairman of Caraco's Board) are secondarily liable for the alleged Section

10(b) and Rule 10b-5 violations stated in Count I of the Amended Complaint because they were "controlling persons." Third, Plaintiffs' Section 20(a) claim fails for several reasons. First, Plaintiffs fail to allege an underlying securities violation. Second, Plaintiffs fail to allege facts that show the purported control persons exercised day-to-day control over Caraco's operations. Third, Plaintiffs fail to allege facts demonstrating that the alleged control persons were "culpable participants" in the alleged fraud.

### A. Plaintiffs fail to allege an underlying securities violation.

For control-person liability to exist, plaintiffs must allege an underlying violation of the securities laws by a primary actor. If a plaintiff fails to establish primary liability for a violation of the securities laws, then there is no predicate act upon which control person liability could be founded. *PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 696 (6th Cir. 2004). In this case, the primary actor is Caraco. Since the Plaintiffs have failed to state a claim for a primary violation of Section 10(b) of the Exchange Act by Caraco, there can be no secondary violation by the remaining Defendants. The Court should therefore dismiss Count II of the Amended Complaint.<sup>19</sup>

# B. <u>Plaintiffs' summary conclusions that a corporate executive, director, and owner are control persons for purposes of Section 20(a) are insufficient.</u>

To state a claim for control-person liability the Plaintiff must allege facts that show that the Defendants other than Caraco (1) "exercised control over the operations of the violator" and (2) "possessed the power to control the transaction or activity upon which the primary violation

42

<sup>&</sup>lt;sup>19</sup> Moreover, Plaintiffs are precluded from simultaneously asserting both Section 10(b) and Section 20(a) claims against the same Defendants. *See PR Diamonds, Inc.*, 364 F.3d at 697 n.4; *see also Kalnit v. Eichler*, 85 F. Supp. 2d 232, 246 (S.D.N.Y. 1999) (dismissing Section 20(a) claim because the defendants were "primary violators . . . who had knowledge of the fraud and assisted in its perpetration") (quotation omitted); *In re Capstead Mortg. Corp. Sec. Litig.*, 258 F. Supp. 2d 533, 566 (N.D. Tex. 2003) ("secondary liability under § 20(a) is an alternative, not a supplement, to primary liability under § 10(b) and Rule 10b-5").

is predicated." *In re Hayes Lemmerz*, 271 F. Supp. 2d at 1021-22. "In order to allege the first element adequately, 'plaintiffs must show that the individual defendant had some indirect means of discipline or influence, even if short of actual direction, over the corporation." *Picard Chem. Inc. Profit Sharing Plan v. Perrigo Co.*, 940 F. Supp. 1101, 1134 (W.D. Mich. 1996) (citing *In re Rospatch Sec. Litig.*, 760 F. Supp. 1239, 1248 (W.D. Mich. 1991)).

Simply stating that the Individual Defendants had "high-level positions" at Caraco is not enough to raise a strong inference of control-person liability. "Status or formal position by themselves will not suffice to state a claim of 'control.'" *Picard Chem. Inc.*, 940 F. Supp. at 1134 (citing *Wool v. Tandem Computers, Inc.*, 818 F.2d 1433, 1441 (9th Cir. 1987)). Courts in this circuit do not impose liability based on titles alone.

In *Frank*, the district court dismissed Section 20(a) claims against corporate executives simply because they were "executives." 649 F. Supp. 2d at 746. Likewise, courts are unwilling to impose liability on a director simply because that person is a director. *Picard Chem. Inc.*, 940 F. Supp. at 1128. Thus, because Plaintiffs have failed to allege particularized facts that show Sun Pharma and the Individual Defendants had "day-to-day" control over Caraco's operations, Plaintiffs Section 20(a) claim fails.

### C. <u>Plaintiffs have not satisfied the culpable participation test.</u>

Finally, to state a claim for control person liability under Section 20(a), Plaintiffs must also allege specific facts demonstrating that Sun Pharma and each of the Individual Defendants were "culpable participants" in the alleged underlying violation. *D.E. & J Ltd. P'ship*, 284 F. Supp. 2d at 750. To allege culpable participation, the Amended Complaint must state (1) particularized facts of the controlling person's conscious misbehavior as a culpable participant in the fraud; or (2) facts giving rise to a strong inference that the controlling person knew or should have known that the primary violator, over whom the person had control, was engaging in

fraudulent conduct. *In re Livent Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 417 (S.D.N.Y. 2001). Plaintiffs make no such allegations.

The Amended Complaint is devoid of particularized allegations of either meaningful participation or culpability on the part of Sun Pharma or the Individual Defendants. Plaintiffs' allegations regarding Sun Pharma are limited to conclusory statements regarding Sun Pharma's alleged exertion of "significant control over Caraco's operations." Am. Compl. ¶ 48. As to the Individual Defendants, Plaintiffs merely offer boilerplate "group" assertions – applicable to any officer or director of any publicly-held company – that Movens and Shanghvi held certain positions within Caraco and therefore knew or should have known of the alleged underlying fraud. Am. Compl. ¶ 29. Such generic allegations are insufficient to plead culpable participation. See Mishkin v. Ageloff, No. 97 Civ. 2690, 1998 WL 651065, at \*26 (S.D.N.Y Sept. 23, 1998). Plaintiffs' control person claims in Count II should be dismissed.

#### **CONCLUSION**

For all of the reasons set forth herein, the Defendants respectfully request that the Court grant their Motion to Dismiss and dismiss the Consolidated Amended Complaint with prejudice.

Dated April 12, 2010

BRIGGS AND MORGAN, P.A.

s/ Frank A. Taylor

Frank A. Taylor Margaret Adamczyk Goetze 2200 IDS Center 80 South Eighth Street Minneapolis, MN 55402 Telephone: (612) 977-8400

Facsimile: (612) 977-8650 ftaylor@briggs.com

mgoetze@briggs.com

Attorneys for Defendants

#### **CERTIFICATE OF SERVICE**

I hereby certify that, on this 12th day of April 2010, I electronically filed the foregoing Motion to Dismiss and Memorandum of Law in Support of Defendants' Motion to Dismiss the Consolidated Amended Class Action Complaint with the Clerk of Court using the ECF system, which will send notification of such filing to the following counsel of record:

- Peter A. Binkow pbinkow@glancylaw.com
- Courtney B. Ciullo cbc@millerlawpc.com
- E. Powell Miller epm@millerlawpc.com
- Marc L. Newman mln@millerlawpc.com
- S. Thomas Wienner twienner@wiennergould.com

s/ Frank A. Taylor

Frank A. Taylor 2200 IDS Center 80 South Eighth Street Minneapolis, MN 55402 Telephone: (612) 977-8400

Facsimile: (612) 977-8650 ftaylor@briggs.com